

**EMORD & ASSOCIATES, P.C.**

1050 SEVENTEENTH STREET, N.W.

SUITE 600

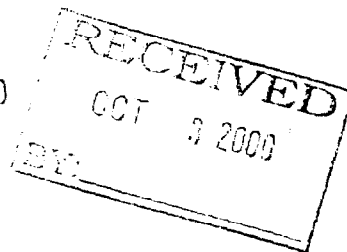
WASHINGTON, D.C. 20036

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September 29, 2000

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**VIA U.S. MAIL**

Christine Lewis, Ph.D.

Office of Special Nutritionals (HFS-450)

Food and Drug Administration

200 C Street, S.W.

Washington, D.C. 20204

**Re: Fulfillment of Reporting Obligation  
Under 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93**

Dear Dr. Lewis:

Rx Vitamins, Inc.,<sup>1</sup> in accordance with 21 U.S.C. § 343(r) and 21 C.F.R. § § 101.93, hereby submits an original and two copies of its notification with the statements presented below. Rx Vitamins retains scientific documentation supporting these statements.

1. **Supplemental Brand Name**  
Testost - Rx
2. **Supplement Ingredients**  
Zinc, Tribulus Terrestris Fruit, Brazilian Muira Puama, Yohimbe, DHEA, Boron, Gelatin, Glycerin, Silica and Water
3. **Text of Statements of Nutritional Support**
  - ✓ Promotes Healthy Testosterone Levels.
  - ✓ Clinical studies suggest that healthy levels of circulating testosterone are associated with increased physical energy and endurance, muscle growth, decreased body fat, mental acuity and peak functioning of the circulatory system.

In accordance with 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold-faced type: **"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."**

Respectfully submitted,

Jonathan W. Emord  
Claudia A. Lewis-Eng  
Kathryn E. Balmford

975-0162

Let 6013

<sup>1</sup> The address for Rx Vitamins is 200 Myrtle Boulevard, Larchmont, NY 10538.

Certification

I, Craig Kisciras, President of Rx Vitamins, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Rx Vitamins has substantiation that the statements are truthful and not misleading.

Executed on:

9/29/00

  
\_\_\_\_\_  
Craig Kisciras